UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. AND BOEHRINGER INGELHEIM INTERNATIONAL GMBH, *Plaintiffs*, v. ANOBRI PHARMACEUTICALS US, LLC, *Defendant*.	Civil Action No. 23-3530 (CCC) (LDW) Civil Action No. 23-3531 (CCC) (LDW) (Consolidated)

STIPULATION AND ORDER

WHEREAS, Anobri Pharmaceuticals US, LLC ("Anobri") submitted Abbreviated New Drug Applications ("ANDA") Nos. 216580 and 216581 to the U.S. Food and Drug Administration ("FDA") under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)) respectively seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of the generic version of the pharmaceutical products COMBIVENT® Respimat®, and SPIRIVA® Respimat® before the expiration of Boehringer's United States Patent Nos. 7,396,341 ("the '6,341 patent"), 9,027,967 ("the '967 patent"), 7,837,235 ("the '235 patent"), and 8,733,341 ("the '3,341 patent") (collectively, "the patents-in-suit");

WHEREAS, Boehringer timely filed suits on June 29, 2023 against Anobri alleging infringement of the patents-in-suits under 35 U.S.C. § 271(e)(2)(A) in the above-captioned actions ("Consolidated Action");

WHEREAS, Anobri's ANDA Nos. 216580 and 216581 are currently subject to a statutory stay of approval, which is currently set to expire on November 19, 2025, assuming that the patents-

in-suit remain in FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book");

WHEREAS, Anobri informed the Court and Boehringer on March 14, 2024 that it planned to make changes to the products for which it seeks approval in ANDA Nos. 216580 and 216581 ("ANDA Products");

WHEREAS, the Court stayed the schedule pending Anobri's ANDA amendments;

WHEREAS, Anobri sent samples, engineering drawings, and quality specifications for the amended component to Boehringer in September 2024, and filed its ANDA amendments in October 2024;

WHEREAS, the parties have agreed that an extension of the statutory stay from November 19, 2025 to July 21, 2026 is appropriate;

WHEREAS, the Court finds that the requirements of 21 U.S.C. § 355(j)(5)(B)(iii) are met;

NOW, THEREFORE, it is hereby stipulated by the parties, and it is hereby **ORDERED** that:

Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the Court hereby extends the statutory stay until July 21, 2026, during which the FDA is barred from approving ANDA Nos. 216580 and 216581.

Notwithstanding this extension, the statutory stay shall be automatically terminated prior to July 21, 2026, if all of the patents-in-suit are delisted in FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), or if the court enters final judgment finding all the patents-in-suit invalid, not enforceable, or not infringed. The statutory stay and this extension shall also be terminated prior to July 21, 2026 for any reason provided for by statute, federal regulation, or other applicable authority, including a written agreement by the

patent owner or the exclusive patent licensee (or their representatives) that ANDA Nos. 216580 and 216581 may be approved, or a settlement between the patent owner and Anobri.

So Ordered on this 26 day of February, 2025

The Honorable Judge Claire C. Cecchi
United States District Court Judge

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